

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Application of Mammone, et al.

Group Art Unit: 1623

Serial No.: 09/925,333

Examiner: WHITE, Everett

Filed: August 9, 2001

For: **METHOD FOR EXFOLIATING SKIN**

RESPONSE TO EXAMINER'S ANSWER

Commissioner of Patents
Attention: Board of Patent Appeals and Interferences
Alexandria, VA 22313-1450

Sir:

In response to the Examiner's Answer of February 27, 2007 to the Appellants' Appeal Brief of November 13, 2006, Appellant respectfully submits the following remarks.

REMARKS

Claims 1, 4-7, 10-14 and 17-19 remain rejected and pending in the application. Claims 2, 3, 8, 9, 15, 16 have been cancelled. The allowance of claims 1 and 4-6 (office action of August 29, 2005) has been withdrawn in the office action of April 25, 2006. The appealed claims (1, 4-7, 10-14, and 17-19) are those of the Response under 37 C.F.R. 1.115, mailed on January 27, 2006, which were entered and considered. On September 19, 2006, following the final rejection of April 25, 2006, the Appellants submitted an amendment to claim 14 for consideration. The amendment was not entered and the accompanying arguments were deemed moot. An Appeal Brief was submitted by the Appellants on November 13, 2006. The Examiner's Answer to the Appellants' Appeal Brief was mailed on February 27, 2007, requesting the Board to sustain the claim rejections.

The invention of independent claim 1 is a method of exfoliating the skin comprising applying to the skin a composition containing an effective amount of a mannose phosphate (see page 2, lines 7-9, 20 and 21 of the specification). The invention of independent claim 7 is a method for increasing levels of glycosaminoglycans in skin comprising applying to the skin in need of such increase a composition containing an effective amount of a mannose phosphate (see page 4, lines 21-23 of the specification). The invention of independent claim 13 is a method of treating a skin condition associated with a reduced level of glycosaminoglycans in the skin comprising applying to the skin afflicted with such a condition a composition containing an effective amount of a mannose phosphate (see page 5, lines 2-5 of the specification).

Claim rejections – 35 USC § 102(b)

The outstanding issues are whether claims 1, and 4-6, drawing to a method of exfoliating the skin, are anticipated by U.S. Patent No. 5,520,926 (Ferguson, hereinafter referred to as "the reference"), whether claims 7 and 10-12, drawn to a method for increasing levels of glycosaminoglycans in skin, are anticipated by the reference, and whether claims 17-19, drawn to a method of treating a skin condition associated with a reduced level of glycosaminoglycans in the skin, are anticipated by the reference.

The questions to be considered are whether the reference, which relates to a method of treating an organism with mannose-6- or 1-phosphate, to prevent or mitigate a fibrotic disorder, places within the possession of the skilled artisan, the methods of the present invention, including a method of exfoliation, comprising applying to the skin a composition containing an effective amount of a mannose phosphate; a method of increasing the level of glycosaminoglycans in the skin, comprising applying to the skin in need of such increase a composition containing an effective amount of a mannose phosphate; and a method of treating a condition associated with reduced levels of glycosaminoglycans in the skin, comprising applying to the skin afflicted with such a condition, a composition containing an effective amount of a mannose phosphate. More specifically, the questions are whether "photodamage" as defined in the reference is the equivalent of "photoaging" as used in the present specification, and whether the subject matter of claims 1 and 4-6 is inherently identical to the subject matter of claims 13 and 14 which allegedly rely on the same mechanism.

Claims 7, 10-14 and 17-19

Claims 7, 10-14 and 17-19 have been rejected under 35 USC §102(b) as being anticipated by the reference. It is the Examiner's position that the teaching in the reference of the use of mannose -6- and 1-phosphates to treat fibrotic disorders anticipates the present claims relating to the use of the same material to stimulate the production of glycosaminoglycans in skin, and to treat conditions associated with reduced levels of glycosaminoglycans, such as skin aging (chrono- or photo). The rejection, stated as follows, is repeated from the office action of August 29, 2005 (rejecting claims 7, 10-14 and 17-19):

Applicants claim method for increasing levels of glycosaminoglycans in skin comprising applying to the skin a composition containing an effective amount of a mannose phosphate. Additional limitations in the dependent claims include the mannose phosphate being mannose-6-phosphate, the use of a specific amount of mannose phosphate, and the method having specific skin conditions, which include dry skin, lines and wrinkles, and symptoms of chrono-and photoaging.

The Ferguson patent discloses mannose 6- and 1-phosphates as being useful in the treatment of fibrotic disorders (see abstract). See column 4, lines 28-31, wherein the Ferguson patent discloses the invention thereof as being 'primarily of interest in relation to skin wounds, whether arising through surgery or other wise, including severe abrasions

laceration and burns, but is also applicable to fibrotic disorders, which includes photo-damage.' See the examples disclosed in the Ferguson patent wherein the amounts of mannose phosphates used in the treatments are disclosed, which appear to be within the scope of the amounts of mannose phosphate set forth in the instant claims. The use of mannose phosphate to treat fibrotic disorders, which include and photo-damage, in the Ferguson patent anticipates the instantly claimed method of increasing levels of glycosaminoglycans in skin, since the instant claims disclose that photoaging of skin is a condition associated with reduced level of glycosaminoglycans in the skin (see instant Claim 14).

The Examiner states further in the office action of April 25, 2006:

Also Applicants argument that there is a difference between the photo-damage skin of the Ferguson patent and the photo-aged skin of the instant claims is not persuasive. Hence Applicants arguments from a legal point of view is not persuasive.

The mannose 6-phosphate applied to skin disclosed in the instant claims is identical to the mannose 6-phosphate applied to skin disclosed in the Ferguson patent. Applicants are reminded that products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims are necessarily present. *In re Spada* 15 USPQ 2d 1655, 1658 (Fed. Cir. 1990). See MPEP 21112.01.

The Appellants responded in their Appeal Brief that the Examiner's position regarding "photo-aging" as the term is used in the art generally, and in the present specification specifically, and "photodamage" as it relates to the reference, is simply incorrect, both technically and legally.

To address the technical error first, equating photoaging with photodamage as these terms are used in the present specification and in the reference, respectively, is based on a misreading of each of the present specification and the reference. As stated in the reference, in column 4, lines 28-33:

Although the invention is primarily of interest in relation to skin wounds, whether arising through surgery or otherwise, including severe abrasions lacerations and burns, it is also applicable to fibrotic skin disorders, e.g. photo-damage (which is believed to up-regulate certain effectors of an increase in fibrous tissue)...[emphasis added].

The fibrotic disorders referred to in the reference are characterized by an excess of fibrous material in the tissues affected. An exemplary list of fibrotic diseases is found in column 1, lines 33-37 in the reference. Unlike the photo-damage disclosed in the

reference, the present specification refers to photo-aging, which includes the symptoms of dry skin, lines and wrinkles. In fact, it is well-known to those skilled in the cosmetic arts as well as in photochemistry and photobiology, that “solar UV radiation damages human skin, affecting skin tone and resiliency, and leading to premature aging (i.e. photo-aging), the symptoms of which include leathery texture, wrinkles, mottled pigmentation, laxity and sallowness”, as stated in the abstract “Molecular mechanisms of photoaging in human skin in vivo and their prevention by all-trans retinoic acid”, published in 1999, submitted with the Appellants’ Appeal Brief and previously submitted with the response mailed September 19, 2006, and the summary entitled “Aging – the skin”, which was submitted with the Appellants’ Appeal Brief and previously submitted with the response of January 27, 2006. As indicated in the abstract, it has been proposed that photo-aging results from UV induction of enzymes which degrade skin collagen (i.e., fibrous material which keeps skin from sagging). Signs of aging skin, as set out in the summary, include wrinkles, sagging, and dryness.

Since “photodamage”, as defined in the reference, and “photoaging”, as used in the present specification and as understood by those skilled in the art, are mutually exclusive conditions, then, strictly from a technical point of view, there is no anticipation of the present claims by the reference.

Similarly, from a legal point of view, the basis for rejection of the claims on the ground of anticipation also fails. Absence of a claim element from a prior art reference negates anticipation. *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 224 USPQ 409 (Fed. Cir. 1984). The Appellants remind the Examiner that a composition comprising a mannose phosphate is not being claimed, and therefore *In re Spada* and MPEP 2112.01 have been misapplied to the present claims. The Appellants are instead claiming a method for increasing levels of glycosaminoglycans in skin, and a method of treating a skin condition associated with a reduced level of glycosaminoglycans in the skin. The reference fails to disclose either a method for increasing levels of glycosaminoglycans in skin or a method of treating a skin condition associated with a reduced level of glycosaminoglycans in the skin. Since the reference fails to disclose each and every element of the claimed inventions, there is no anticipation of the present claims by the reference.

The Appellants also argued that should the Examiner's basis of rejection be anticipation based on inherency, then this also fails. For the concept of inherency to apply in an anticipation rejection, the subject matter being claimed must undeniably and irrefutably flow from the prior art disclosure. *Hughes aircraft Co. v. United States*, 8 USPQ 2d 1580 (Ct. Cl. 1988). Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstance is not sufficient. *In re Oelrich and Divigard*, 212 USPQ 323 (CCPA) 1981). The "photo-damaged" tissue to which a mannose phosphate would be applied according to the reference (tissue exhibiting fibrotic disorders) is clearly not the photoaged skin to which a mannose phosphate would be applied according to the methods of the present invention (dry and/or wrinkled skin associated with aging). Therefore, the result claimed in the present application would not "irrefutably flow" from the disclosure of the reference. Because the present invention addresses the application of the mannose phosphate to a type of tissue (photoaged) skin which is different from the tissue (exhibiting fibrotic disease) disclosed in the reference, there can be no anticipation of the present claims by the reference. See *Perricone v. Medicis Pharmaceutical Corporation*, 77 USPQ2d 1321, 1328 (CAFC, 2005), where the application of a known composition to "sunburned" skin was found to be patentable over the application of the same composition to skin generally.

In response to the Appellants' arguments, submitted in their Appeal Brief, addressing the Examiner's technical position, the Examiner states in his Answer the following:

Appellant's arguments filed November 13, 2006 in the Appeal Brief have been fully considered but they are not persuasive. Appellant argue against the rejection on the ground that the Examiner's position regarding "photoaging" as the term is used in the art generally, and in the present specification, and "photodamage" as it relates to the Ferguson patent, is incorrect. This argument is not persuasive in view of the Journal of American Academy of Dermatology, 1996; Vol. 35. [pages 462-464, which is titled "Guidelines of Care for Photoaging Photodamage". In this article under subheading "II. Definition", the article discloses that "photoageing and photodamage (dermatoheliosis) are term used interchangeable to describe those chronic changes in the appearance and function of the skin caused by repeated sun exposure". In this session of the article it is disclosed that "photodamage may be chronic or acute and that acute photodamage is a sunburn". The article continue on to disclose that "overwhelming epidemiologic and laboratory evidence

indicates that sun exposure and other sources of UV radiation (UVR) play the major role in causing the undesirable skin changes of fine and coarse wrinkles, roughness, laxity, mottled pigmentation, actinic lentigines, actinic keratoses, leathery texture/coarseness, scaling/xerosis, sallowness, and telangiectasia." This article presented by the American Academy of Dermatology show that the teachings disclosed in the Ferguson patent and in the instant application are not distinct, and that the terms "photodamage" and "photoaging" are not mutually exclusive conditions.

The Examiner further states that the "article is not being used to reject the instant claims (not being used to present a new ground of rejection)...only intended to assist in rebutting Appellant's arguments".

The Appellants cannot agree that the article supports the position taken by the Examiner. This particular article suggests that the field of Dermatology equates the terms "photodamage" and "photoaging". On the other hand, the Appellants have submitted an abstract with the Appeal Brief indicating that, in the field of Photochemistry and Photobiology, the definition of photoaging refers to premature aging of the skin and the symptoms associated therewith. Notwithstanding the different uses of the terms in the various practice areas, the Applicants maintain that the definitions of photodamage and photoaging, as these terms are used respectively in the Ferguson reference and in the present specification, are mutually exclusive. "Photoaging" as used in the present specification refers to the symptoms of dry skin, lines and wrinkles, and to the related symptoms of solar UV radiation damage of human skin, affecting skin tone and resiliency, and leading to premature aging (i.e. photo-aging), including leathery texture, wrinkles, mottled pigmentation, laxity and sallowness, as discussed in the materials submitted with the Appellants' Brief. In fact, these are the very same effects of photodamage/photoaging which are the subject matter of the article presented by the Examiner (dry skin, lines and wrinkles, liver spots, scaling, coarsened texture, etc.). Nothing disclosed in that article teaches or suggests the definition of photodamage given in the Ferguson patent. The reference specifically states, in column 4, lines 28-33, "Although the invention is primarily of interest in relation to skin wounds,...including severe abrasions lacerations and burns, it is also applicable to fibrotic skin disorders, e.g. photo-damage (which is believed to up-regulate certain effectors of an increase in fibrous tissue)..." (emphasis added). Further, in column 1, lines 33-37, these fibrotic disorders are listed and include glomerulonephritis, cirrhosis of the liver, fibrocytic

disease, fibrosis, fibrotic cancers, fibroids, fibroadenomas and fibrosarcomas. These are serious pathological conditions associated with fibrosis (pathological lesions) in the affected tissue. Such conditions and their symptoms cannot in anyway be equated with the photoaging symptoms described in the present specification or in the Journal of American Academy of Dermatology article presented by the Examiner with his Answer. The Appellants therefore maintain that “photodamage” and “photoaging”, as used in the Ferguson reference and in the present specification, respectively, are mutually exclusive conditions, and therefore there can be no anticipation of the present claims by the Ferguson reference.

In response to the Appellants’ arguments, submitted in their Appeal Brief, addressing the Examiner’s legal position, the Examiner states the following:

Appellant also argue that *in re Spada* and MPEP 2112.02 has been misapplied to the present claims since the instant claims are directed to a process. This argument is not persuasive since the instantly claimed inventions only disclosed a process step that involve the administration of the product (mannose phosphate) to the skin, in order to accomplish the limitation recited in the preambles of the instant claims. No multiple process steps are recited in the instants claims, which means that the mannose phosphate is only required to have the properties disclosed in the preambles of the instant claims. The Ferguson patent, which does disclose the administration of mannose phosphate to the skin, does indeed have the properties recited in the preamble of the instant claims, since the mannose phosphate of the Ferguson patent and cited in the instant claims are substantially the same. Perhaps, Appellant may have a greater appreciation for *In re King*, 801, F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986), which states – Under the principles of inherency, if a prior art device (in the instant case mannose phosphate), in its normal and usual operation (in the instant case, administered to the skin), would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art device. When the prior art device is the same as a device described in the specification for carrying out the claimed methods, it can be assume d the device will inherently perform the claimed process.

The Appellants cannot agree with the position taken by the Examiner. The Appellants arguments with regard to *In re Spada* have already been presented above. Furthermore, *In re King* can be distinguished from the present case. The issue in *In re King* was whether an article of manufacture in the prior art can be used to support an anticipation rejection of method claims that, in essence, simply define what happens

when that article of manufacture is placed in the environment in which the article will be used. Therefore, that case concerned method claims directed to the normal and usual function of a known device. In the present case, the Appellants claim new methods of using a prior art composition; that is, a method of increasing the levels of glycosaminoglycans in skin by applying to skin in need of such increase a composition containing an effective amount of a mannose phosphate, and a method of treating a skin condition associated with a reduced level of glycosaminoglycans in the skin comprising applying to the skin afflicted with such a condition a composition containing an effective amount of a mannose phosphate (present claims 7 and 13, respectively). Thus, the presently claimed methods are not those recited in the reference since they claim methods neither disclosed nor contemplated in the reference and call for the application of mannose phosphate to completely different populations of users than those populations disclosed in the reference. As stated in *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161,163 (CCPA 1957), cited in *In re King*, “As a matter of claim drafting, therefore, the discoverer of a new use must protect his discovery by means of process or method claims and not product claims.” The Appellants have done just that.

Moreover, the preambles of the Appellants’ claims limit their scope as they are necessary to “give life, meaning, and vitality to the [claims]” *Catalina Mktg. Int’l, Inc. v. Coolsavings Com., Inc.*, 289 F.3d, 801, 808 (Fed. Cir. 2002) (citing *Pitney Bowes, Inc. v. Hewlett-Packards, Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999)). In present claim 7, the preamble gives meaning, life and vitality to the step of “applying to the skin in need of such increase an effective amount of a mannose phosphate”. Similarly, in present claim 13, the preamble gives meaning, life and vitality to the step of “applying to the skin afflicted with such a condition an effective amount of a mannose phosphate”. Additionally, as discussed above, because the present invention addresses application of the mannose phosphate to a type of skin different from that disclosed in the reference (e.g., skin in need of an increase in the level of glycosaminoglycans, skin afflicted with the conditions of a reduced level of glycosaminoglycans), there can be no anticipation of the present claims by the reference. See *Perricone v. Medicis Pharmaceutical Corporation*, 77 USPQ2.D 1321 (CAFC 2005), wherein the application of a composition to “sunburned” skin was found to be patentable over the application of the same composition to skin generally. The Court in *Perricone* stated “the issue is not...whether Pereira’s lotion *if applied* to skin sunburn would inherently treat that damage, but

whether Pereira discloses the application of its composition to skin sunburn. It does not...This court explained in *Catalina Marketing International, Inc. v. Cool Savings.com, Inc.* that a patent to an apparatus does not necessarily prevent a subsequent inventor from obtaining a patent on a new method of using the apparatus. 289 F.3d 801, 809 [62 USPQ2d 1781] (Fed. Cir. 2002). New uses of old products or processes are indeed patentable subject matter. See 35 U.S.C. §101 (2000) (identifying as patentable 'any new and useful improvements' of a process, machine, manufacture, etc.); *In re King*, 801 F.2d 1324, 1326 [231 USPQ 136] (Fed. Cir. 1986) (principles of inherency do not prohibit a process patent for a new use of an old structure). That principle governs in this case as well."

The Appellants have noted that the Examiner's Answer does not address the Appellants' arguments regarding the refusal of the Examiner, in the Advisory Action of November 1, 2006, to enter the amendment to claim 14. The Advisory Action indicates that the proposed amendment to claim 14 will not be entered because the amendment raises new issues that would require further consideration and/or search, the amendment is not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal, and the amendment presents additional claims without canceling a corresponding number of finally rejected claims. The Examiner further comments as follows:

The amendment filed September 19, 2006 also will not be enter because the metes and bounds of the phrase "other symptoms of chrono- and photoaging" cannot be determined which renders Claim 14 indefinite.

The Appellants restate herein that the position of the Examiner is untenable. The amendment to claim 14, as discussed in the response of September 19, 2006, was presented to bring about conformity with the disclosure in the present specification at page 5, lines 2-5, and thereby to place the application in better form for appeal by simplifying the issue for appeal, i.e. whether "photoaging" as used in the present specification, is equivalent to "photodamage" defined in the reference. The amendment was presented to change "the" to "other" before "symptoms" to correct an apparent typographical error, thus making it clear that dry skin, lines and wrinkles are some of the symptoms of chrono- and photoaging – the symptoms with which the present invention is primarily concerned. As discussed above, the reference most specifically defines

“photo-damage” in column 4, lines 28-33, as effecting an increase in fibrous tissue manifested in fibrotic skin disorders, and provides an exemplary list of fibrotic diseases in column 1, lines 33-37. On the other hand, the present specification addresses the symptoms of “photoaging”, including dry skin, lines and wrinkles. By increasing the level of glycosaminoglycans in the skin, which help to retain moisture in the skin, the present invention relieves dryness and also plumps the skin to thereby reduce the appearance of lines and wrinkles and other symptoms of chrono- and photoaging (see page 2, lines 16-18, and page 4, line 28 – page 5, line 5). The amendment to claim 14, proposed in the previous response, was intended to make it clear that the aforementioned symptoms of dryness, lines and wrinkles are characteristic of photoaging and are not separate conditions therefrom. In view of this disclosure in the present specification, at page 5, lines 3-5, the amendment to claim 14 would require no further consideration and/or search. The claims must be definite when read in light of the specification. *In re Moore*, 169 USPQ 236 (CCPA 1971). Although the proposed amendment is fairly based on the application as filed, in further support of the Applicants' position, the response filed on September 19, 2006 included an abstract which discusses photoaging in human skin, more specifically, the symptoms of premature aging (also referred to in the abstract as photoaging) associated with solar UV radiation damage to the skin. The abstract provides a non-exhaustive list of five symptoms. The abstract was again presented in the Evidence Appendix of the Appellants' Brief. It is well-established that a specification need not disclose, and in fact, preferably omits, that which is already known in the art. *Hybridtech Inc v. Monoclonal Antibodies, Inc.*, 231 USPQ 81 (Fed. Circ. 1986). For these reasons, it still is the Appellants' position that claim 14, if amended to refer to “other symptoms of chrono- and photoaging”, would be rendered more definite, and not indefinite.

Also not addressed by the Examiner in his Answer was that the Advisory Action incorrectly advised the Applicants that new claims were presented without a corresponding cancellation of claims; however, as no new claims had been presented, no corresponding number of finally rejected claims was required.

In view of the technical and legal arguments presented above, it is clear that the rejection of claims 7, 10-14 and 17-19 as anticipated by the reference is improper and should be withdrawn.

Claims 1 and 4-6

Claims 1 and 4-6 also have been rejected under 35 USC §102(b) as being anticipated by the reference. It is the Examiner's position that the teaching in the reference of the use of mannose -6- and 1-phosphates to treat fibrotic disorders anticipates the claims 1 and 4-6 relating to the use of the same material to exfoliate skin. The rejection, in the office action of April 25, 2006, is stated as follows:

The method of exfoliating skin comprising applying to the skin a composition comprising mannose phosphate and the application of mannose phosphate for the treatment of photoaging skin are based on the same principle that involves removing the outmost layer of skin and replacing the outer layer with newly generated skin cells. Hence, upon further consideration, the subject of Claims 1 and 4-6 is inherently identical to the method of Claims 13 and 14 since the same mechanism used to carry out the subject matter of Claims 1 and 4-6 is identical to the mechanism used in Claims 13 and 14.

The Appellants argued in their Brief that the Examiner's reasoning for withdrawing the allowability of claims 1 and 4-6, drawn to a method of exfoliating the skin was untenable. The Examiner contends that if claims 7, 10-14, and 17-19 are not allowable for the reasons given, then claims 1 and 4-6 also are not allowable because the methods are inherently the same as the method of claims 7, 10-14, and 17-19. Nevertheless, the Appellants are not claiming a method of applying a mannose phosphate to the skin, generally. The Appellants are claiming, in claim 1, a method of exfoliating the skin which supplements the natural sloughing process, and smoothes the surface texture of the skin, as measured by a reduction in flakiness. On the other hand, claim 13 is directed to a method of treating a skin condition associated with a reduced level of glycosaminoglycans in the skin. The enhanced synthesis of glycosaminoglycans results in increased water retention in the skin and skin plumping with a reduction in the appearance of lines and wrinkles. The respective populations of users of the two methods are not necessarily the same. The population of users having flakey skin in need of exfoliation will not necessarily be that population having dry, and/or wrinkled skin associated with aging. Young skin may exhibit flakiness, due, for example, to tanning, or the use of chemical peels and/or anti-acne agents. Dry skin, resulting from photo-aging, may not necessarily be flakey. Furthermore, the population of users having mature, photo-aged skin, and who are desirous of obtaining plumped skin which will reduce the

appearance of dryness, lines and wrinkles, and sagging of the skin, will also not necessarily be the same population merely in need of exfoliation for treating flakey skin.

From a legal standpoint, there can be no anticipation of claims 1 and 4-6 by the reference. The Appellants are not claiming a composition comprising a mannose phosphate but a method of exfoliating the skin. The reference fails to teach either explicitly or implicitly a method of exfoliating the skin comprising applying to the skin a composition containing an effective amount of a mannose phosphate. A method of exfoliating the skin (e.g. treating flakey skin), as presently claimed, is not the same as the treatment of skin wounds or tissue exhibiting fibrotic disease described in the reference. As the reference fails to disclose each and every element of the claimed invention, there can be no anticipation of claims 1 and 4-6 by the reference. Because the present invention addresses the application of the mannose phosphate to a type of skin different from that disclosed in the reference, there also can be no implicit anticipation of claims 1 and 4-6 by the reference. The tissue to which a mannose phosphate would be applied according to the reference (skin exhibiting wounds or tissue exhibiting fibrotic disease) clearly is not necessarily the same skin in need of exfoliation. Therefore, the result claimed in the present application would not “irrefutably flow” from the disclosure in the reference.

In response to the Appellants’ arguments presented in their Appeal Brief, the Examiner states:

Appellant also argue that the method of exfoliating skin disclosed in instant Claims 1 and 4-6 is distinct from the methods disclosed in the Ferguson patent and the instant claims drawn to methods of increasing levels of glycosaminoglycans in skin and treating a skin condition associated with a reduced level of glycosaminoglycans by describing the population of users in instant Claims 1 and 4-6 as having “flakey” skin. This argument is not persuasive since the method of claims 1 and 4-6 does not require the skin to be flakey.

Appellant further argues that “am method of exfoliating the skin (e.g. treating flakey skin) is not the same as the treatment of skin wound or tissue exhibiting fibrotic disease.” It appears that Appellant is attempting to insert a new definition of ‘exfoliation’ that is not supported by the specification. Again, the claims merely require the application of mannose phosphate to skin—any skin, in the case of claims 1 and 4-6 or ‘photoaged ‘ skin, in the case of claims 7,m10-14 and 17-19. There is no requirement that the skin in question be ‘flakey.’ Therefore, the

application of mannose phosphate to photoaged skin, as taught by Ferguson, anticipates the instant claims.

In contrast to the assertion of the Examiner, the Appellants are not attempting to insert a new definition of exfoliation into the specification. As discussed in the present specification, at page 4, lines 1, 2, "In a representative test, mannose-6-phosphate used at 1% reduced skin **flakiness**, a common measure of exfoliation efficacy...". Further, at page 4, lines 8-10, it is stated "In particular, the formulation may be applied on an as-needed-basis, to 'resurface' skin that is temporarily afflicted with a patchy, **flaky** or irregular texture." See also Example I, pages 5,6 of the present specification wherein it was observed that the "greater difference in % change from baseline between treated and untreated sites, the greater the reduction in skin **flakiness**, and therefore the greater the efficacy in desquamation....results obtained indicate that the mannose-6-phosphate containing composition significantly reduced skin **flakiness**..."

The Appellants also object to the Examiner's statement that there is no requirement that the skin in question be flakey. The Appellants refer to the discussion of the relationship between flakiness and exfoliation in the present specification and point out above that it is well known to those skilled in the art to use reduction in skin flakiness to measure exfoliation efficacy. Moreover, it is well-established that the claims must be definite when read in light of the specification. *In re Moore*, 169 USPQ 236 (CCPA 1971). It is clear that claims 1 and 4-6 are directed to a method of exfoliating the skin, which is neither disclosed nor contemplated by the reference. Furthermore, the method requires the step of applying "an effective amount" of mannose phosphate to the skin to achieve the exfoliation. In this case, the preamble gives life, meaning and vitality to the claims. See *Catalina Marketing International, Inc. v. Cool Savings.com, Inc.*, 289 F.3d 801, 809 (Fed. Cir. 2002). One skilled in the art would appreciate that the method of present claim 1 requires the step of applying the mannose phosphate to skin in need of exfoliation, e.g., flakey skin, and that this method is not inherently taught in the reference.

In view of the arguments presented above, it is clear that the rejection of claims 1 and 4-6 as anticipated by the reference is improper and should be withdrawn.

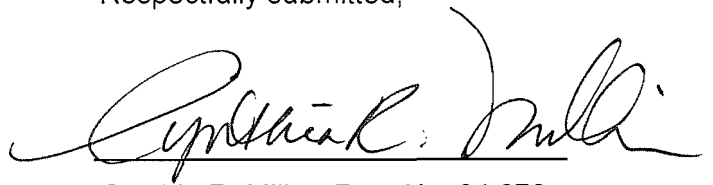
CONCLUSION

In view of the arguments presented above, the rejections of claims 1 and 4-6; and 7, 10-14 and 17-19, as anticipated by the reference must be withdrawn. The reference fails to teach any of the claimed methods, either explicitly or implicitly. The "photo-damage" defined in the reference is not equivalent to the "photoaging" defined in the present specification, and the claimed method of exfoliation is not identical to the claimed method of increasing the level of glycosaminoglycans in skin. Moreover, the application of a mannose phosphate to skin wounds or to ameliorate the effects of fibrotic disorders resulting from photo-damage, as defined in the reference, would not necessarily anticipate the application of a mannose phosphate to flaky skin or to skin exhibiting the signs of photoaging. In view of the arguments presented above, it is believed that independent claims 1, 7 and 13, and the claims dependent therefrom, are patentable over the reference, and that the application is in condition for allowance.

A petition and fee for extension of time for one month is being submitted concurrently with this response.

Respectfully submitted,

Date: May 23, 2007



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